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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,247	07/13/2000	Michael Zasloff	036870-5062-01	5537

9629 7590 03/08/2007

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	03/08/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/885,247
Filing Date: July 13, 2000
Appellant(s): ZASLOFF ET AL.

Gregory T. Lowen
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/27/2006 appealing from the Office action mailed 6/26/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Zasloff et al. (US Patent 5,792,635)

Zasloff et al. (US Patent 5,840,740)

Merck Manual of Diagnosis and Therapy (17th Edition)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zasloff et al. (5,792,635) or Zasloff et al. (5,840,740) in view of the Merck Manual of Diagnosis and Therapy (17th ED).

Zasloff et al. (5,792,635) discloses that administering the instant compound, compound 1436 (see its structure at col. 9-10, 115-116, 159) with a pharmaceutically

acceptable carrier (see col. 4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic. and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col. 1 line 63-65; col. 2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col.83, Table 11), which is within the instant claimed range.

Zasloff et al. (5,840,740) discloses that administering the instant compound, compound 412 (see its structure at col. 41-42) and compound 1436 (see col. 9-10) with a pharmaceutically acceptable carrier (see col. 4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col . 4 line 5-15; col .1 line 63-65; col.2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col. 79, Table 11), which is within the instant claimed range.

Zasloff et al. do not expressly disclose the employment of the compound therein in a method of reducing blood cholesterol levels in a mammal or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Note that Zasloff's method treats atherosclerosis in a mammal since atherosclerosis is a known generic term for diseases including cardiac infarction, angina pectoris and ischemic disorders of the head, and ateriosclerotic diseases, and diabetic

composition and diabetes, hypercholesteremia and hypertension in a mammal (see the the Merck Manual of Diagnosis and Therapy, 17th ED page 1654-1656). The Merck Manual of Diagnosis and Therapy also teaches that elevated serum cholesterol or hypercholesterol, hypertension diabetes mellitus, and obesity are the major risk factors for atherosclerosis (see page 1656 both left and right column entitled by "Risk Factors" and subtitles "Hypertension" "Diabetes mellitus" and "obesity).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Zasloff et al., in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

One having ordinary skill in the ad at the time the invention was made would have been motivated to employ the particular compound of Zasloff et al., in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes, since the prior art compounds are known to be used in treating cardiac infarction, angina pectoris and ischemic disorders of the head, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal. Moreover, elevated serum cholesterol or hypercholesteremia, hypertension, diabetes mellitus, and obesity are well known major risk factors for atherosclerosis and associated with atherosclerosis according to The Merck Manual of Diagnosis and Therapy.

Therefore, one of ordinary skill in the art would have reasonably expected that the prior art compounds, would have beneficial therapeutic effects and usefulness in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Moreover, the patient population for atherosclerosis or diabetes or cardiac infarction, angina pectoris and ischemic disorders of the heart, is reasonably interpreted to encompass or overlap or coincide those patients suffering elevated serum cholesterol as claimed herein, in particular those hypercholesteremia associated with atherosclerosis or diabetes.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

(10) Response to Argument

Appellant argues that a prima facie case of obviousness has not been established because the skilled artisan would not have a reasonable expectation of success of using the aminosterols in claim 14 to reduce blood cholesterol levels in a mammal suffering from hypercholesteremia. For one, the successful treatment of a specific risk factor such as hypercholesteremia by selected aminosterols cannot be reasonably expected simply because some aminosterols may be successful in treating a disease state that may have resulted from the risk factor. Secondly, Appellant argues that the experiments described by Zasloff regarding aminosterols only relate to anti-proliferative or vasodilative effects and not reduced serum cholesterols levels.

This is not persuasive because the rejection has clearly made of prima facie case of obviousness because Zasloff teach the treatment of atherosclerosis by administering the claimed aminosterols. The Merck Manual clearly teaches that elevated serum cholesterol levels are major risk factors for atherosclerosis. Therefore, since the patient population of atherosclerosis is reasonably interpreted to encompass or overlap or coincide with those patients suffering from elevated serum cholesterol levels, it is reasonably expected that aminosterols would be successful in treating hypercholesteremia. Furthermore, Examiner reminds Appellant that the standard for obviousness is not absolute but a reasonable expectation of success.

Appellant argues that since aminosterols were observed to increase glucose levels in the Zasloff reference, it would actually teach against using aminosterols in persons suffering from diabetes, since elevated blood glucose levels are often indicative of diabetes.

Examiner reminds Appellant that the prior art references clearly disclose the treatment of diabetes, among many other diseases, through the inhibition of NHEs by aminosterols. Examiner also reminds Applicant that "reducing blood cholesterol levels" and "reducing blood glucose levels" are considered preamble and will be given little patentable weight. The claims are drawn to method of treating a mammal suffering from hypercholesteremia or diabetes.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is

capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Yong S. Chong, Ph.D.
Patent Examiner
Art Unit 1617

ysc
February 27, 2007

Conferees:

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